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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,767	09/30/2003	Dean DellaPenna	920905.90024	5481

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EXAMINER	
KALLIS, RUSSELL	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,767	DELLAPENNA ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-21 and 26-38* is/are pending in the application.

4a) Of the above claim(s) *15,19-31 and 34-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,14,16-18,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *11/09/2006*.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *attachment #1 (2 pages)*.

DETAILED ACTION

Election/Restrictions

The restriction requirement of 9/07/2006 is hereby **VACATED** in view of the following restriction requirement.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 13-14, 16-18 and 20, drawn to plants and seeds having increased or altered production of gamma tocopherol by transformation with gamma tocopherol methyl transferase and plants and methods thereby, classified in class 800, subclass 288 for example.

II. Claims 17-18, 20-21 and 27-36, drawn to plants and seeds having increased or altered production of alpha tocopherol by transformation with gamma tocopherol methyl transferase and methods thereby, classified in class 800, subclass 28, for example.

III. Claims 15, 19, 21 and 26, drawn to oil from seeds, classified in class 424, subclass 776 for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are the transformed plants and seeds having increased or altered gamma tocopherol of Group I and the transformed plants and seeds having increased or altered alpha tocopherol of Group II drawn to plants having different phenotypes.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are the transformed plants and seeds having increased or altered gamma tocopherol of Group I and the oil of Group III; wherein the oil of Group III does not share the same structure, function or chemical composition of the transformed pants and seeds of Group I and does not comprise the tDNA of the plants and seeds of Group I.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are and the transformed plants and seeds having increased or altered alpha tocopherol of Group II and the oil of Group III; wherein the oil of Group III does not share the same structure, function or chemical composition of the transformed pants and seeds of Group II and does not comprise the tDNA of the plants and seeds of Group II.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, require a different field of search (see MPEP § 808.02), and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Sara Vinarov on 11/09/2006 a provisional election was made with traverse to prosecute the invention of Group I, claim13-14, 16-18 and 32-33. Affirmation of this election must be made by applicant in replying to this Office action. Claims

15, 19-21 and 27-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Claims 13-21 and 26-38 are pending. Claims 15, 19-3134-36 are withdrawn. Claims 13-14, 16-18 and 32-33 are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-14, 17-18 and 32-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to transgenic plants and seeds that have been altered to have gamma tocopherol as the dominant species of tocopherol and plants latered by transformation with a polynucleotide encoding a polypeptide having at least 35% or 61% sequence identity to SEQ ID NO: 4.

Applicants describe polynucleotides of SEQ ID NO: 1 and SEQ ID NO: 3 encoding polypeptides EQ ID NO: 2 and SEQ ID NO: 4 respectively.

Applicants do not describe any transgenic plants altered to produce gamma tocopherol as the dominant tocopherol species in transformed seeds other than transgenic plants comprising SEQ ID NO: 1 or 3; or any polynucleotides encoding SEQ ID NO: 2 or 4 other than SEQ ID NO: 1 and 3.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of

cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide encoding polypeptides having at least 35% or 61% sequence identity to SEQ ID NO: 2 or 4 possessing gamma methyl tocopherol transferase activity. Applicants only describe SEQ ID NO: 1 and 3 encoding SEQ ID NO: 2 and 4. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of gamma methyl tocopherol transferases. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for gamma methyl tocopherol transferase activity, it remains unclear what features identify a gamma methyl tocopherol transferase. Since the genus of gamma methyl tocopherol transferases has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Sequences that have at least 35% or 61% sequence identity to SEQ ID NO: 4 or 2 encompass naturally occurring allelic variants, mutants of SEQ ID NO: 4 or 2, as well as sequences encoding proteins having no known gamma methyl tocopherol transferase activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of gamma methyl tocopherol transferases encompassed by the percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,429,356 (Shewmaker et al.) that claims priority to U.S. Provisional 60/024,145 filed 9 August 1996.

Patent 6,429,356 teaches altered profile of tocopherols in the seeds of transformed plant (see 2 page attached provisional 60/024,145; pages 23-24; especially page 24 Table 2); and thus the reference teaches all the limitations of Claims 17-18.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-14, 16-18 and 32-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 9-11 of U.S. Patent No. 6,642,434. Although the conflicting claims are not identical, they are not patentably distinct from each other because the transgenic plants and seeds comprising a gamma tocopherol methyl transferase gene of the instant application where gamma tocopherol is the most abundant tocopherol species in transformed seeds is obvious over the transgenic plants and seeds of U.S. Patent 6,642,434 comprising a gamma tocopherol methyl transferase of SEQ ID NO: 1 or 3 having an altered alpha:gamma tocopherol ratio and seeds thereof.

All claims are rejected.

Claims 13-14, 16 and 32-33 are deemed free of the prior art given the failure of the prior art to teach or reasonable suggest a transgenic plant or seed comprising SEQ ID NO: 1 or SEQ ID NO: 3; or transgenic plants and seeds that have been altered to have gamma tocopherol as the dominant species of tocopherol when compared to the wild type plant or seeds

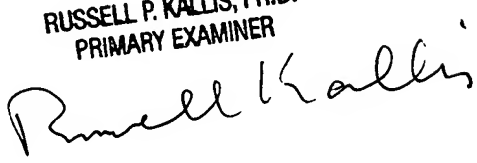
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Russell Kalis Ph.D.
November 23, 2006

RUSSELL P. KALLIS, PH.D.
PRIMARY EXAMINER



The water solution was then extracted twice more with 100µl of ether and the ether samples pooled and washed with water.

The saponified samples were then analyzed by HPLC analysis on a Rainin microsorb C18 column (25cm length, 4.6mm outside diameter) at a flow rate of 1.5ml per minute. The gradient used for elution is as follows:

A = acetonitrile

B = hexane/methylene chloride (1:1)

C = methanol.

The initial solution was 70:20:10 (A:B:C). At 2.5 minutes the solution is ramped over 5 minutes to 65:25:10 (A:B:C) and held at this for 12.5 minutes. The solution is then ramped to 70:20:10 (A:B:C) over two minutes followed by a three minute delay prior to injection of the next sample. The absorbance of the eluting samples is continuously monitored at 450 and 280 nm and known chemical and biological standards were used to identify the various absorbance peaks.

In Figures 3 and 4, results of analyses of saponified samples are provided for control and pCGN3390 transformed seeds, respectively. Clear increases in the levels of α- and ß-carotene and phytoene in the transagenic plant seeds are observed, as well as smaller increases in levels of the hydroxylated carotenoid, lutein.

C. Carotenoid and Tocopherol Analysis of Mature Seeds

Mature T2 seed were sent to an analytical laboratory for quantitative analysis using standard HPLC methods known in the art. These results of these analysis are shown in Table 2 below. Compound levels are presented as µg/g.

Seeds designated "Maroon" were selected based on seed color. The seeds which have orange embryos appear maroon colored at maturity as opposed to the black-brown appearance of seeds from wild type plants of this cultivar. Seeds designated as "Random" were not selected for color. As 3390-1 is segregating 3 to 1 for Kan, the "Random"

population includes a proportion of nulls. The maroon population contains only transgenics. Due to an effort to exclude nulls from this population, the inclusion of homozygotes may be favored.

TABLE 2

COMPOUND	CONTROL	3390-1 RANDOM	3390-1 MAROON
Lutein	7.2	18	26
Zeaxanthin	nd*	nd	nd
α-cryptoxanthin	nd	8	15
β-cryptoxanthin	nd	nd	nd
Lycopene	nd	2.3	5.1
cis-Lycopene	nd	2.9	5.4
α-carotene	0.6	124	244
β-carotene	0.9	177	338
cis-ß-carotene	0.2	12	26
Other	6	34	51
Total colored carotenoids	14.9	378.2	710.5
Phytoene	nd	62	139
Phytofluene	nd	24	54
Total all carotenoids	14.9	464.2	903.5
Alpha-tocopherol	74	93	109
Gamma-tocopherol	246	188	95
Delta-tocopherol	3	5	5

*nd = not detected

In the non-transgenic sample, "other" includes mostly very polar compounds, such as neoxanthin, violaxanthin, etc. In the transgenic sample "other" includes these and additional compounds, such as zeta-carotene, neurosporene, and mono-cyclic carotenoids.